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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,248	09/30/2003	Peter K. Rogan	33026	5913

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EXAMINER	
WONG, JENNIFER SHIN SHIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,248	ROGAN ET AL.	
	Examiner	Art Unit	
	Jennifer Wong	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-11, 20-33 drawn to nucleic acids, classified in class 536, subclass 23.1.

   II. Claims 12-19, drawn to methods to develop single copy DNA probes, classified in class 435, subclass 6.

   III. Claims 34-40, drawn to methods of diagnosing chromosomal abnormalities, classified in Class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the nucleic acids of invention I can be isolated from its natural source.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acids of invention I can be used in a materially different process such as for synthesizing nucleic acids or proteins as well as for diagnostic therapies.

Inventions II and IIII are drawn to patentably distinct methods, having different process steps, involving the use of different reagents and having different objectives. The methods of invention II require the use of nucleic acids, computers, and software, and involve experimental assays and computer analysis, to determine single copy interval sequences, and the synthesis of single copy nucleic acids to accomplish the objective of developing single copy DNA probes. On the other hand, the methods of invention III, require the use of nucleic acids and involve hybridization assays in order to accomplish the objective of detecting hybridization patterns as a diagnostic of genetic abnormalities. The methods of invention II and III are novel and unobvious over one another. The methods of invention II and III are novel and unobvious over one another.

3. Further, should Applicants elect invention I, this group is subject to an additional restriction requirement as follows.

Claims 5,8,10, 22, 24, and 33 is subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

Claims 2-4, 6,7,9,11,21, 23, 25, 28-32 link the individual sequences of 5,8,10, 22, 24, and 33 as each sequence comprises a distinct invention as outlined above. Each of these nucleic acid sequences consist of nucleotides which determine their structure, properties, and function.

Given the differences in structure and function, the Markush group set forth in claims 5,8,10, 22, 24, and 33 are not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. Nucleic acid sequences and each molecule containing the nucleic acid sequence is distinct from each of the other nucleic acid sequence. For example, polynucleotide comprising SEQ ID NO: 23 is chemically, structurally and functionally distinct from a polynucleotide comprising SEQ ID NO: 86. Further, a search for a nucleic acid comprising a SEQ ID NO: 23 would not be co-extensive with a search for a nucleic acid comprising SEQ ID NO: 81. Additionally, a reference which renders obvious a SEQ ID NO: 23 will not necessarily also render obvious a different SEQ ID NO: 81. Similarly, a search indicating that SEQ ID NO: 23 is novel or unobvious would not extend to a holding that SEQ ID NO: 81 is also unobvious.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0.

The claims of invention I are broadly drawn towards nucleic acids. With respect to claims 1-11, 20-25, and 27-33, the claims encompass probes of the nucleic acids of SEQ ID NO: 1-23, 26-36, 38-57, 59-61, 63-67, 69-82 and 245-251. With respect to claim 26, the claims encompass primer pairs of SEQ ID NO: 83-244.

The nucleic acid probes set forth in SEQ ID NO: 1-23, 26-36, 38-57, 59-61, 63-67, 69-82 and 245-251, and the primers set forth in Table 2 consist of distinct nucleotide sequences, and a further restriction is applied to each invention. Applicants must elect a single probe with its corresponding chromosome OR one primer pair to be examined.

It is noted that each nucleic acid sequence constitute distinct chemical compounds and each has a distinct functional property. The chemical structure of each nucleic acid sequence and of each molecule containing the nucleic acid sequence is distinct from each of the other nucleic acid sequence. Nucleic acid sequences consist of nucleotides and which determine its structure, properties and function.
For example, a polynucleotide comprising SEQ ID NO: 23 is chemically, structurally and functionally distinct from a polynucleotide comprising SEQ ID NO: 86. Further, a search for a nucleic acid comprising a SEQ ID NO: 23 would not be co-extensive with a search for a nucleic acid comprising SEQ ID NO: 81. Additionally, a reference which renders obvious a SEQ ID NO: 23 will not necessarily also render obvious a different SEQ ID NO: 81. Similarly, a search indicating that SEQ ID NO: 23 is novel or unobvious would

not extend to a holding that SEQ ID NO: 81 is also unobvious. Likewise a primer pair for one chromosome is chemically, structurally and functionally distinct from another primer pair of a different chromosome. Each of these primers consists of a distinct nucleic acid sequence, has a different melting point, and binds to a different nucleic acid sequence, and thereby has a different biological function. Given the differences in structure and function, the Markush group set forth in claim 26 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A search for a primer pair of SEQ ID NO 3 and 4:

CCCTAAACTCCTCCCTATCCCTTCTCAATC and

AAAAAAAACCTCATTTCCTCCCCAAAGC respectively would not be co-extensive with a search for a primer pair of comprising SEQ ID NO 9 and 10:

CAGAGCATAGTCAAGAGAGGCGCATTTTCC and

AAGAGCCCCTAAATTAGCCCCGTAGAAACC respectively. Additionally, a reference which renders obvious a SEQ ID NO: 3 and 4 will not necessarily also render obvious a different SEQ ID NO: 9 and 10. Similarly, a search indicating that SEQ ID NO: 3 and 4 is novel or unobvious would not extend to a holding that 9 and 10 is also unobvious.

Accordingly, the nucleic acid sequence and primer pair are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid sequence and primer pair are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In summary, should Applicant elect invention I, Applicant is required to elect either a single probe with its corresponding chromosome OR one primer pair.

4. Further, should Applicants elect invention II, this group is subject to an additional restriction requirement as follows.

Claim 18 is subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

Claims 2-9, 12-17 and 19 link the individual sequences of claim 18 as each sequencing comprising a distinct invention as outlined above. Each of these nucleic acid sequences consists of nucleotides and which determine its structure, properties and function.

Given the differences in structure and function, the Markush group set forth in claim 18 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. Nucleic acid sequence and have each molecule containing the nucleic acid sequence is distinct from each of the other nucleic acid sequence. Nucleic acid sequences consist of nucleotides and which determine its structure, properties and function. For example, a polynucleotide comprising SEQ ID NO: 23 is chemically, structurally and functionally distinct from a polynucleotide comprising SEQ ID NO: 67. Further, a search for a nucleic acid comprising a SEQ ID NO: 23 would not be co-extensive with a search for a nucleic acid comprising SEQ ID NO: 67. Additionally, a reference which renders obvious a SEQ ID

NO: 23 will not necessarily also render obvious a different SEQ ID NO: 67. Similarly, a search indicating that SEQ ID NO: 23 is novel or unobvious would not extend to a holding that SEQ ID NO: 67 is also unobvious. In summary, should Applicant elect invention II, Applicant is required to elect a single probe with its corresponding chromosome

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0.

6. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-III require different searches that are not co-extensive. For instance, a literature and sequence search of the nucleic acids of invention I is not coextensive with a patent and keyword search for the methods of inventions of developing single copy DNA probes of invention II, the diagnostic methods of invention III. A finding that the nucleic acids of invention I is anticipated or obvious does not extend to a finding that the methods of inventions II and III are also anticipated and obvious. Similarly, a finding that the nucleic acids of invention I is novel and unobvious does not necessarily extend to a finding that the methods of invention II are III are also novel and unobvious. Likewise, a keyword and sequence search of the methods to develop a single copy probe of invention II is not coextensive with a keyword and patent search for the diagnostic methods of invention III. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise**

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. A telephone call was made to Tracy Truitt on January 24, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Wong whose telephone number is (571) 272-1120. The examiner can normally be reached on Monday-Friday; 8 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Wong

CARLA J. MYERS
PRIMARY EXAMINER